

REMARKS

Claims 1-22 and 28-32 remain in the application. Claims 1-21, 28, 29, 31, and 32 are withdrawn from consideration. Only claims 30 and 32 are in independent form.

Claim 30 stands rejected under 35 U.S.C. §103(a) as being unpatentable over van Hoogdalem, et al. in view of Raskin for the reasons set forth in the Office Action dated October, 2, 2006. Specifically, the Office Action states that van Hoogdalem, et al. teaches rectal drug administration of various drug formulations such as valproate suppository. The reference teaches using valproic acid or sodium valproate formulated as suppository for treatment of epilepsy, which reads on the method consisting of the step of administering an effective amount of medication in a suppository into the rectum of an individual. Van Hoogdalem, et al. does not teach using the valproate suppository to treat migraine. However, Raskin teaches using valproate sodium for treatment of migraine and that valproate sodium appears to be remarkably effective in treating migraine. Therefore, it would have been obvious for one of skill in the art to use valproate in the form of a suppository to treat migraine, one skilled in the art would have been motivated to use valproate in the form of a suppository to treat migraine because it has been shown to be effective in treating migraine, and one skilled in the art would have a reasonable expectation of success because valproate has successfully been formulated into and administered as suppositories and has been shown to effectively treat migraine. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over the van Hoogdalem, et al. reference in combination with the Raskin reference is respectfully requested.

The van Hoogdalem reference teaches the use of valproic acid or sodium valproate as a suppository. Van Hoogdalem does not teach anything about migraine headaches and their treatment – the sodium valproate was only administered to healthy volunteers and epileptic children. Thus, there is no evidence that sodium valproate would work effectively as a migraine headache treatment. Raskin teaches that valproate sodium in a tablet can be used as a migraine treatment, as shown in Table 1, and is stated that it "appears to be remarkably effective" (p. 302). Raskin also states that oral agents may suffice and that only when oral agents fail, are rectal, parenteral, and intravenous agents administered. Raskin proceeds to describe several treatments that are not effective or that produce unwanted side effects when administered orally such as ergotamine tartrate, dihydroergotamine mesylate, and chlorpromazine hydrochloride. Valproate sodium is not one of such treatments. There is no indication from Raskin that valproate sodium will not be effective in oral dosage form, and thus there is no motivation to use a suppository form. Further, there is not any data available in the prior art that valproate sodium is effective in suppository form as a treatment for migraines, and therefore there is no motivation to combine these references to arrive at the present invention. Therefore, the combination of van Hoogdalem, et al. and Riskin would not arrive at the present invention as claimed in independent claim 30.

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully submitted that the claims are clearly patentable over the combination, even if the combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.

Claim 30 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Sorensen, in view of U.S. Patent No. 5,500,221 to Murata (hereinafter the '221 patent) for the reasons set forth in the Office Action dated February 21, 2006. The Office Action states with respect to Applicant's previous argument that the '221 patent does not disclose the suppository without the inclusion of additional compositions, that such a limitation is not recited in the rejected claims. The Office Action holds that Sorensen teaches using valproate to treat migraine but does not specifically teach the valproate or its salts administered as a suppository. However, the '221 patent discloses a formulation of valproate and its salts in a suppository, as well as the advantages of formulating drugs into suppositories. Therefore, it would have been obvious for one skilled in the art to make valproate in the form of a suppository to treat migraine, a person skilled in the art would have been motivated to use valproate in the form of a suppository to treat migraine because of the advantages of suppositories, and a person skilled in the art would have a reasonable expectation of success of achieving such modifications because valproate and its salts have been successfully formulated into suppositories as taught by the '221 patent, and valproate has been shown to effectively treat migraine as taught by Sorensen. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over the Sorensen, et al. reference in combination with the '221 patent is respectfully requested.

Sorensen, et al. teaches the *oral* administration of valproate as a *prophylactic* treatment of migraines, i.e. preventing and not treating upon occurrence. See p. 347 – "The results of the present study demonstrate that valproate has a considerable effect as prophylactic in treatment of severe migraine." There is no suggestion or motivation based on Sorensen, et al. to use a suppository form of valproate, since the oral dosage form is so effective. The '221 patent discloses a sustained-release suppository comprising sodium

valproate and an acidic compound or pH buffering agent but does not disclose its use as a migraine treatment. The '221 patent uses open language and thus sodium valproate can be combined with other agents. Applicant has amended claim 30 to have closed language as suggested by the Office Action. No new material has been added by this amendment. Further, Applicant uses valproate as a treatment, not as a prophylactic. Therefore, the combination of Sorensen, et al. and the '221 patent would not arrive at the invention as defined in amended independent claim 30, namely, treating a migraine headache by the administration of a medication consisting essentially of a compound selected from the group consisting of valproate, sodium valproate, and valproate salts in a pharmaceutical acceptable carrier within a suppository into a rectum of an individual.

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully submitted that the claims are clearly patentable over the combination, even if the combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.

Claims 22 and 30 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Office Action holds that it is not clear if each of the recited medications is in a pharmaceutically acceptable carrier or if only valproate salts are in a pharmaceutically acceptable carrier. In response thereto, Applicant has amended the claims to clarify that the medication is in a pharmaceutically acceptable carrier in the suppository. Reconsideration of the rejection is respectfully requested.

Claim 22 stands rejected under 35 U.S.C. § 102(b), as being anticipated by the '221 patent. Specifically, the Office Action holds that the '221 patent discloses a suppository preparation comprising a therapeutically effective amount of an acidic drug or a pharmaceutically acceptable salt thereof which can be absorbed by rectal administration, wherein the acidic drug is sodium valproate. The '221 patent further discloses that the suppository preparation contains other additives. Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by the '221 patent, as applied to the claim, is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

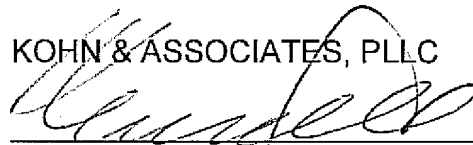
Applicant has amended claim 22 to have closed language and therefore does not read on the '221 patent. The '221 patent does not teach a medication consisting essentially of a compound selected from the group consisting of valproate, sodium valproate, and valproate salts in a pharmaceutical acceptable carrier within a suppository. Reconsideration of the rejection under 35 U.S.C. §102(b) is respectfully requested.

In conclusion, it is respectfully submitted the application is in condition for allowance, which allowance is respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

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Connie Herty